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(54) IMPLANTABLE SURGICAL PIPELINE

(71) We, SOCIETE DES INDUSTRIES PLASTIQUES - SODIP, a French body corporate of 7, Avenue Lionel Terray, 69330 Meyzieu, France,

do hereby declare the invention for which we pray that a patent may be granted to us, and the method by which it is to be performed, to be particularly described in and by the following statement:-

The present invention relates to implantable surgical pipelines. These pipelines can be used, in particular, as a prosthesis for replacing a natural pipeline, as an arterio-venous shunt or as a prosthesis giving access to the vessels.

The replacement of biological pipelines gives rise to numerous problems, in particular if the pressure of the fluid inside the pipeline is insufficient to allow the pipeline to be re-opened after collapse of the wall; in that case it is necessary to produce pipelines, the wall of which possesses means for radial elastic return which are sufficient to allow the pipeline to be re-opened after collapse of the wall without requiring internal pressure to be applied.

An attempt has been made to solve this problem by providing a transverse corrugation in the wall of the pipeline. Pipelines, of which the wall has corrugations in that case have the disadvantage of being difficult to colonise by the living tissues. In fact, inernal colonisation is poor since the corrugations can move relative to each other and these movements cause the rupture of the colonising film.

In addition, some causes of failure of the replacement of natural pipelines by non-resorbable prostheses are due to poor tolerance in the long term, that is to say after several months' implantation, shown by the surrounding living tissues towards the materials constituting the prosthesis, and this can give rise either to infections or to intolerance phenomena, such as the formation of granulomas or to an excessive reaction to a foreign body.

An attempt has therefore been made to solve this problem by producing knitted or woven prostheses which are coated with collagen in order to bring about immediate leak-proofness to the fluid. A disadvantage of these prostheses is that the collagen disappears too rapidly before a pipeline of new tissues is properly formed.

According to the present invention there is provided an implantable surgical pipeline for the flow of fluid, said pipeline comprising a tube having flexible walls and suturable ends, the flexible wall being formed of at least one layer of material which is resorbable material but which is not completely resorbable until after at least six months implantation and reinforcing means extending along the length of the flexible wall for maintaining a radially resilient tube construction, the tube construction being of substantially constant cross section along its length.

Such an implantable biological pipeline offers sufficient resistance to crushing and returns to its initial cross-section after collapse of the wall. There are no sudden changes in the cross-section of the pipeline and the pipeline remains flexible without kinking.

In order that the invention will be better understood the following description is given, merely by way of example, reference being made to the accompanying drawings, in which:-

Figure 1 is a perspective view of a length of one embodiment of pipeline according to the invention;

Figure 2 is a view in section through a plane perpendicular to the axis of the pipeline of Figure 1; and

Figures 3, 4, 5 and *6* are perspective views of four more embodiments of pipeline according to the invention.

The implantable pipeline which will be described below has a wall which comprises at least one layer of resorbable material which is not completely resorbed until after at least six months implantation.

This material has a flexible structure which can adopt a plane or cylindrical shape, it being possible for this structure to be of the fibrous or non-fibrous type.

Amongst the material having a structure of the fibrous type there may be mentioned more particularly the fabrics.

By "fabric" there is understood, in the following text, an assembly, which may or may not be regular, of fibres and/or filaments and/or single filament or multifilament yarns, which are employed separately or simultaneously. This assembly may be obtained by intermingling, for example by knitting, crocheting, weaving or by braiding, or by interlacing, or by assembling webs of fibres, yarns or filaments, which are firmly fixed to one another in order to obtain a non-woven fabric.

Amongst the non-fibrous materials there may be mentioned flexible and for example permeable films or "membranes".

The non-fibrous materials may initially have a plane shape and can subsequently be given the shape of a pipeline, for example by welding; they can also be obtained directly in a cylindrical shape.

The porous material which can be used in the invention have a thickness which is generally between 30 μ and 3 mm, preferably between 100 μ and 1mm.

Although a structure with non-connecting pores can be used, it is, however, advantageous in the invention to use a structure having open pores, that is to say possessing small rectilinear or winding channels which pass right through the material. Of course, in the present text, the term "pores" should be understood in its widest sense; this means that micropores, macropores, holes and open structures such as are found between the fibres of a fabric web are included in the term pores. The pores used are of a size which is generally between 10 Å and 2 mm, and preferably between 0.01 and 50 μ.

The invention will be described below with reference to a pipeline of which the wall is constituted by a fabric.

The implantable pipeline 1 shown in Figures 1 and 2 is substantially cylindrical and has a flexible wall 2, formed by a fabric rolled upon itself in such a way that, in section through a plane perpendicular to the axis of the pipeline, the wall of the pipeline is of spiral form formed by two layers 3 and 4. The two layers 3, 4 can be firmly fixed to each other at 5 by any known means, such as, for example, by gluing, by welding, for example by ultrasonic welding, or by sewing. At each of its ends, the implantable pipeline can have a bead 7, which is formed by the fabric constituting the wall being folded over outwards; this bead facilitates suturing the implantable pipeline to the existing biological pipelines.

The layers 3 and 4 are furthermore firmly fixed to one another along one or more helices by welding, for example by ultrasonic welding.

The welded zones 12 are therefore more compact and more rigid than the wall of the pipeline and thus constitute the reinforcing means. It is, or course, understood that these pipelines are made of fabrics comprising thermoplastic fibres, or fabrics of which the surfaces have been coated with thermoplastic materials.

The welded helices can have the same direction or opposite directions and advantageously have the same pitch. The pitch of the welded helices is between 0.1 and 10 times, preferably between 0.2 and 5 times, the diameter of the pipeline.

The fabric forming the wall of implantable pipelines according to this first embodiment can consist of natural and/or artificial and/or synthetic fibres. It is possible to use, for example, fabrics made of nylon, a fluorinated polymer (in particular polytetrafluoroethylene), polyvinyl chloride or a polyester (in particular polyglycol terephthalate), the last product being generally preferred.

If desired, it is possible to produce such implantable pipelines in accordance with the method which will be described below by way of example.

A rectangle of which the dimensions are about one centimetre greater than the length of the pipeline, on the one hand, and about one centimetre greater than double the perimeter of the pipeline, on the other hand, is cut out of the fabric selected to produce the pipeline. The rectangle is rolled up lengthwise in relation to the pipeline on a cylindrical mandrel, the latter thus being covered wth two layers of fabric and an overlap zone formed by a third layer of width approximately one centimetre. Ultrasonic welding is carried out, moving the electrode along a generatrix of the mandrel, within the overlap zone formed by the third layer.

The tube thus obtained is removed from the mandrel, the excess fabric protruding beyond the weld on the outer surface is cut off and the excess on the inner surface is then cut off after turning the tube inside out.

The tube is placed on the mandrel, the beads are formed by turning over the ends, and the beads are fixed by welding, round a full circle of the tube, by rotating the mandrel about its axis.

The welding head, for example, is then shifted with a rectilinear movement along a

generatrix of the mandrel and the latter is at the same time caused to undergo a rotary motion about its axis in such a way that the layers of fabric forming the wall of the tube are welded along a first helix. The speeds of the rectilinear and rotary movements are of course determined in accordance with the selected pitch and angle of the helix. The operation is repeated, giving the mandrel a rotary movement in the opposite direction, and the two layers are welded along a second helix having the same pitch and the same angle as the first but being in the opposite direction. The pipeline obtained is then removed from the mandrel. After the checking, conditioning and, optionally, sterilising operations, the implantable pipeline is ready for use.

It is also possible to produce implantable pipelines which are only formed from one layer of fabric. The fabric forming the wall is in that case caused to undergo partial fusion along one or more helices. This partial fusion can be achieved by heating, for example by ultrasonic heating. The fused zone, which is more compact and more rigid than the initial fabric, thus forms the reinforcing means.

Pipelines according to the invention are made at least partially of materials which are resorbable in the long term. These pipelines thus constitute a support for the reformation of a new pipeline, for example by the formation of an endothelium of an epithelium. Whilst this formation is in progress, after several months of implantation the material which at least partially constitutes the wall is gradually resorbed so as to leave only living tissues. Advantageously, it is desirable for part of the prosthesis not to be resorbed and to provide the newly formed pipeline with the mechanical strength required to avoid tearing. The pipelines of the invention therefore, have reinforcing means which are resorbable only with difficulty or are made of non-resorbable material.

The implantable surgical pipelines described above and shown in Figures 1 and 2 are produced from a material which is resorbable in the long term. As a result of their compactness, the welded or fused zones are resorbed less quickly than the fabric constituting the wall of the pipeline and thus serve as reinforcing means.

It is also possible to produce implantable surgical pipelines which have a wall made of a material which is resorbable in the long term and reinforcing means made of a non-resorbable material. Various embodiments of such pipelines are shown in Figures 3 to 6 and are described below.

The implantable pipeline 1 shown in Figure 3 has a wall 2 similar to that of the pipeline shown in Figures 1 and 2. The reinforcing means 6 consist in this case of a filiform element arranged essentially in a helix and positioned alternately on the outer surface and then on the inner surface of the pipeline, after it has passed through the wall of the pipeline in a manner similar to a tacking thread.

The filiform elements can also be positioned entirely on the outer surface of the pipeline. In that case, they can be firmly fixed to the wall of the pipeline, for example by gluing or by partial fusion of the elements.

The pipeline can also have a bead 7 similar to that described above, in order to facilitate suturing the implantable pipeline to the existing biological pipelines.

The filiform reinforcing element is generally of circular cross-section but it can optionally be of rectangular cross-section, similar to a tape, and be arranged in such a way that the largest dimension of the cross-section is substantially tangential to the cylinder of the pipeline.

It is possible to use polyester or polyamide bristles or bristles made of a thermosetting material in order to produce filiform reinforcing elements of circular cross-section.

The filiform reinforcing element can be arranged in the shape of a helix of which the diameter is substantially the same as the diameter of the pipeline, the pitch of the spiral being between 0.1 and 10 times, preferably between 0.2 and 5 times, the diameter of the pipeline.

The implantable pipeline may optionally have several filiform reinforcing elements arranged in helices having the same hand or opposite hand and advantageously having the same pitch.

The reinforcing means may optionally, as shown in Figure 4, consist of longitudinal filiform elements 8 combined with transverse filiform elements 9. The longitudinal elements which are preferably resilient, are essentially positioned along the generatrices of the pipeline, the transverse elements being positioned in planes which may or may not be perpendicular to the axis of the pipeline.

As shown in Figure 5, it is also possible to fix the filiform element firmly to the wall of the pipeline by means of at least one supplementary thread. The implantable pipeline 1 shown has, like the pipelines described above, a flexible wall 2 and a filiform reinforcing element 6 formed in this case by a bristle, for example a polyester bristle, arranged in a helix on the pipeline. The bristle 6 is firmly fixed to the wall of the pipeline by means of at least one supplementary thread 10 which fixes the bristle to the pipeline along at least one generatrix of the pipeline, by means of back-stitches 11

surrounding the bristle. The back-stitches are of course spaced over the generatrix at a distance equal to the pitch of the helix. The supplementary thread may optionally be thermoplastic and thus provide for spot-gluing of the bristle.

It is also possible to produce implantable pipelines of which the reinforcing means consist of a loose structure made of threads, filaments or fibres, for example of polyester or polyamide or even a thermosetting material. By loose structure there is understood a structure which leaves spaces greater than 1 mm^2 between the threads, fibres or filaments. The loose structure may be woven, knitted, crocheted, interlaced or braided, and may be obtained by the customary methods. It may also consist of a net.

Figure 6 shows a pipeline according to the invention, the reinforcing means of which consist of a loose structure 13 which in this case is woven.

Reinforcing means of this kind are advantageously located on the outer surface of the pipeline and they can be firmly fixed to the wall of the said pipeline, for example by gluing or by partial fusion.

If desired, it is also possble to produce a pipeline according to the invention by arranging the reinforcing elements in the actual wall of the pipeline, between two superposed layers of fabrics. Reinforcing elements of this kind are advantageously made of a thermoplastic material and the two layers are firmly fixed together by partial fusion of the reinforcing elements, for example by heating in an oven.

Implantable pipelines which have a wall made of a material which is resorbable in the long term and reinforcing means made of a non-resorbable material can also be obtained directly by weaving, knitting, crocheting, interlacing or braiding threads and/or fibres and/or filaments made of a resorbable material together with threads and/or fibres and/or filaments made of a non-resorbable material, for example of polyester or polyamide or even a thermosetting material.

The material from which the implantable biological pipelines are produced and are resorbable in the long term i.e. after at least six months, may be formed from fibres of a polycondensate of glycollic acid or of lactic acid, or of a polycondensate of glycollic acid and lactic acid. It is also possible to use fibres of an alkylene polysuccinate or alkylene polyoxalate or of a mixture of an alkylene polysuccinate and polyoxalate, or of a copolycondensate of an alkylene oxalate and an alkylene succinate.

The material which is resorbable in the long term and which constitutes the wall of the pipeline must, of course, be selected so that its rate of resorption is suited to the rate of regeneration of the living tissue replaced. Thus, during the course of the resorption, the fabric constituting the wall of the pipeline is replaced by living tissues which thus reconstruct a new natural pipeline. The non-resorbable reinforcing elements thus form a reinforcement which improves the mechanical properties of the reconstructed natural pipeline.

The wall of the implantable pipeline may comprise one or more layers of fabric. The number of layers is selected depending on the texture of the fabric employed, and on the elasticity and thickness desired for the implantable pipeline.

For biological pipelines which convey blood, a fabric will preferably be selected which is not water-tight but which rapidly becomes fluid-tight when it is impregnated with blood which coagulates between its fibres. The fibrin which is thus deposited on the inner surface of the pipeline will serve as a support for the film of colonising tissue. A pipeline made of an excessively porous fabric may be covered on its outer surface with a water-repellent film, such as a silicone film, which will avoid a haemorrhage as a result of bleeding.

The inner surface of the pipeline which is in contact with the blood should preferably be able to be easily impregnated with the blood; the inner surface of the pipeline advantageously has the appearance of a velour.

It is optionally possible to replace the bead 7 by a textile sleeve which can be made of any colonisable material, for example similar to those materials constituting the wall of the pipeline. The textile sleeve is generally a tubular knitted fabric but it can also be, for example, a napped fabric or a cut velour. The textile sleeve can be fixed to the pipeline by sewing or by gluing along its edges or, preferably, over its entire surface. The partial impregnation of the sleeve with glue can be complemented, if desired, by an impregnation in depth with a suitable diluted solution of elastomers.

The pipeline according to the invention may optionally comprise at least one radio-opaque element. This element may be arranged, for example, in the wall, along a generatrix of the pipeline, and may also be arranged at the ends, in the suturing beads. The reinforcing elements may optionally be made of a radio-opaque material.

As the radio-opaque material, it is possible to use, in particular, compounds containing heavy metals, such as barium or bismuth. The material constituting the wall of the pipeline may also contain the radio-opaque material which is introduced into the bulk (of the material).

The invention is of course in no way restricted to the embodiments described

specifically in the present text and variants or improvements relating to the various means employed may be adapted without thereby going outside the scope of the present invention. It is of course also understood that the embodiments described above can be combined with each other.

Pipelines according to the invention can be produced in various dimensions. Pipelines with a diameter between 1 and 40 mm, preferably between 2 and 30 mm, are generally suitable and the length of such pipelines can range from a few millimetres to lengths of the order of a metre.

Implantable pipelines are also contemplated which are in the shape of a truncated cone or have one or more branches. Pipelines having branches can be produced in sections which are then assembled, for example by sewing or by welding, for example by ultrasonic welding.

The implantable pipelines according to the present invention have numerous advantages. In fact, these pipelines are flexible and can thus easily follow the shape of the adjacent organs, and the presence of the reinforcing means allows them to retain a passage for the fluid as the pipelines are deformed. In addition, the reinforcing means prevent the pipeline from becoming plicated, for example when the pipeline has to follow the movement of a joint. The reinforcing means furthermore prevent the pipeline from kinking, especially during the implantation operation.

The presence of the reinforcing means gives the pipeline sufficient radial resilient return to allow it to reopen after collapse of the wall, without requiring internal pressure to be applied. This resilient property is particularly valuable when the pipeline is employed as a prosthesis for a vein, since the pressure of the venous blood is not sufficient to reopen the pipeline after collapse of the wall.

The artificial pipelines according to the invention preferably have a uniform wall, that is to say there is no sudden change in the cross-section of the pipeline, and this facilitates the flow of the fluid conveyed and avoids vortices and the occurrence of dead zones or preferential zones which encourage deposits and incipient coagulation, in particular if the fluid conveyed is blood. In pipelines of this kind, the flow is very even and this has the advantage of giving good reproduction of the conditions of flow in the veins, where the flow is virtually laminar.

Artificial pipelines of which the wall consists of a polymer which is resorbable in the long term possess, in addition to the above advantages, the advantage of reducing the intolerance phenomena which may make it necessary to remove the pipeline.

Thus, for example, an artificial pipeline according to the invention was implanted in dogs as a vascular prosthesis. The wall of this artificial pipeline consists of a crocheted fabric of polytetramethylene succinate and the inner surface of the pipeline had the appearance of a velour. It is provided with reinforcing means consisting of a polyester bristle having a diameter of 5/10 of a millimetre, the reinforcing means being firmly fixed to the wall of the pipeline by partial fusion.

After six months' implantation, it was found that a vascular endothelium covered the inner surface of the pipeline. The fact that, after this reconstruction phase, the major part of the pipeline was resorbed avoided the complications frequently encountered, such as infection which can arise at the point of contact with the foreign material. In addition, after resorption the reinforcing means which remained avoided the risks of the newly formed living tissues dilating and rupturing. Thus, when the pipeline was used as a prosthesis for an artery, the reinforcing means which remain after resorption prevent the formation of an aneurism.

The implantable pipelines according to the present invention can be used to convey biological fluids and can in particular be used as a prosthesis for natural biological pipelines.

These pipelines can be used to convey blood. In that case they are used as a prosthesis for a vein or an artery, or as an arterio-venous shunt, or as a prosthesis giving access to the vessels.

They can also be used to convey urine and in that case they are used as a prosthesis for a urethra or as a prosthesis for a ureter.

They can also convey bile and in that case they are used as a prosthesis for the choledoch duct.

It is also possible to use the pipelines according to the invention to convey foodstuffs and in that case they replace a part of the digestive system, for example as a prosthesis for the oesophagus.

The pipelines according to the invention can also convey air and in that case they are used, for example, as a prosthesis for the trachea.

WHAT WE CLAIM IS:

1. An implantable surgical pipeline for the flow of fluid, said pipeline comprising a tube having flexible walls and suturable ends, the flexible wall being formed of at least one layer of material which is resorbable material but which is not completely resorbable until after at least six months implantation and reinforcing means extending along the length of the flexible wall for maintaining a radially resilient tube construction, the tube construction being of substantially constant cross-section along its

length.

2. A pipeline according to Claim 1, in which the layer is made of a polycondensate of glycolic acid or lactic acid or of glycolic or lactic acid.

3. A pipeline according to Claim 1, in which the layer is made of an alkylene polyoxalate or of an alkylene polysuccinate of or a mixture of alkylene polyoxalate and polysuccinate.

4. A pipeline according to Claim 1, in which the layer is made of copolycondensate of an alkylene oxalate and an alkylene succinate.

5. A pipeline according to Claim 1, in which the layer is made of a polyester.

6. A pipeline according to any preceding claim, in which the reinforcing means comprise longitudinal elements associated with transverse elements.

7. A pipeline according to any preceding claim, in which the reinforcing means comprise at least one separate element.

8. A pipeline according to claim 7, in which the element or elements are firmly fixed to the wall of the tube.

9. A pipeline according to claim 8, in which the elements are firmly fixed to the wall of the tube by passing alternately over the outer surface and then over the inner surface of the tube, by passing through the tube wall.

10. A pipeline according to claim 8, in which the elements are firmly fixed to the wall of the tube by means of at least one supplementary thread.

11. A pipeline according to claim 10, in which the supplementary thread firmly fixes the elements to the pipeline by means of back-stitches surrounding the elements.

12. A pipeline according to any one of claims 7 to 11, in which the elements are filiform.

13. A pipeline according to any one of claims 7 to 11, in which the elements consist of a tape.

14. A pipeline according to any one of claims 7 to 11, in which the reinforcing means consist of a loose structure.

15. A pipeline according to any one of claims 7 to 14, in which the reinforcing elements are made of a polyester.

16. A pipeline according to any preceding claim, in which at least two layers of material form the flexible wall, the reinforcing means comprising means which serve to fix the layers firmly to each other.

17. A pipeline according to claim 12, in which the layers are firmly fixed to each other by welding.

18. A pipeline according to claim 16 or 17, in which the layers are firmly fixed to each other along at least one helix.

19. A pipeline according to claim 16 or 17, in which the layers are firmly fixed to each other along several helices having the same pitch and having the same direction and/or opposite direction.

20. A pipeline according to claim 18 or 19, in which several elements are arranged in helices having the same pitch and having the same direction and/or opposite direction.

21. A pipeline according to claim 18, 19 or 20, in which the pitch of the helix or helices is between 0.1 and 10 times the diameter of the tube.

22. A pipeline according to claim 21, in which the pitch of the helices is equal to the diameter of the tube.

23. A pipeline according to any one of the preceding claims, in which the layer of material is a fabric.

24. An implantable surgical pipeline substantially as hereinbefore described with reference to and as illustrated in Figures 1 and 2 or any one of Figures 3 to 6 of the accompanying drawings.

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1565828 COMPLETE SPECIFICATION

2 SHEETS

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Sheet 1

Fig. 1

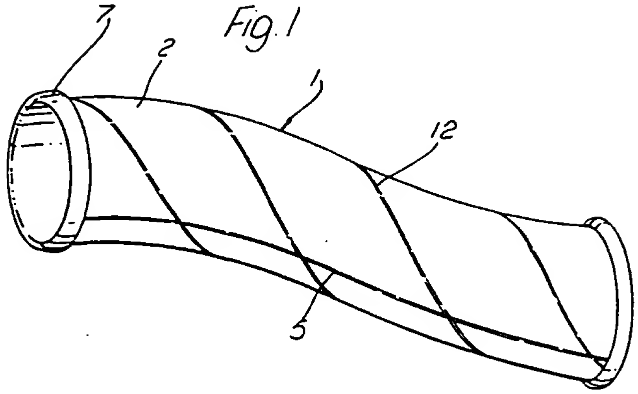


Fig. 2

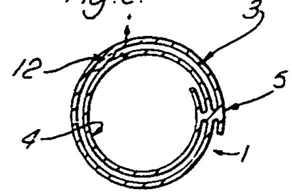


Fig. 3.

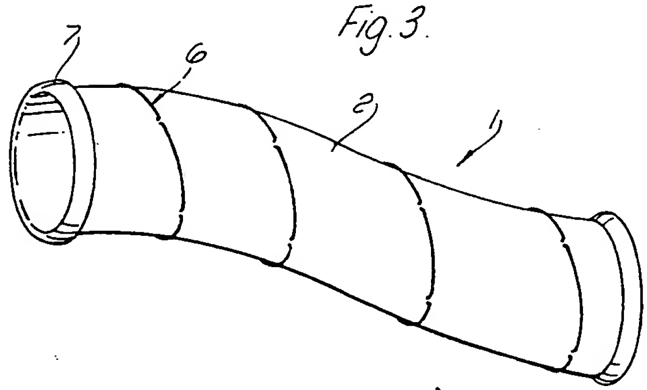


Fig. 4

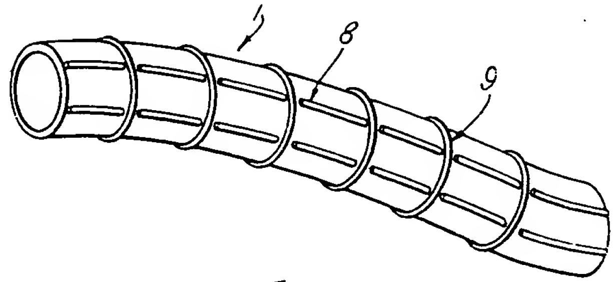


Fig. 5.

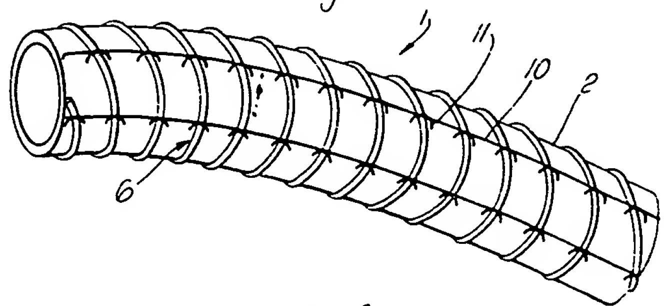
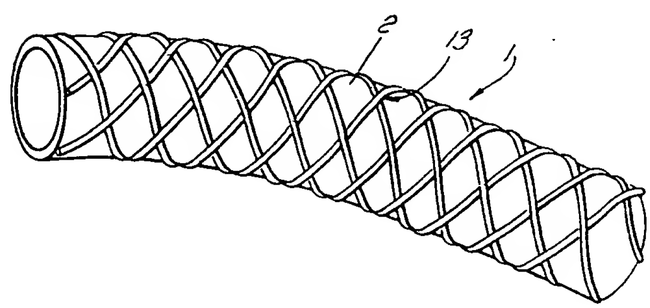


Fig. 6.



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